



REGULATORY PHARMACEUTICAL FELLOWSHIP

Government | Industry | Academia

2016 – 2018

Jointly sponsored by:



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FELLOWSHIP OBJECTIVES

- ❖ Train selected candidates via a two-year, knowledge-based program on medical and regulatory aspects of drug information dissemination, advertising and promotion or medication safety
- ❖ Maintain and enhance a scientific link among the Food and Drug Administration (FDA), academia, and the pharmaceutical industry
- ❖ Offer opportunities for fellows to understand the complex participating roles of the FDA and the pharmaceutical industry in the delivery of drug information and the regulatory oversight of prescription drug marketing and safety practices
- ❖ Provide participants the opportunity to experience careers in the areas of government, academia, and industry
- ❖ Qualify program graduates to pursue careers in each unique practice area
- ❖ **The 2016 – 2018 program cycle will be recruiting for the following fellowship tracks:
Drug Information & Medication Safety**



PROGRAM DIRECTOR



Lindsay E. Wagner, PharmD

Lieutenant Commander, U.S. Public Health Service

Team Leader

Division of Drug Information
Food and Drug Administration

Drug Information Track Preceptor
Past Fellow: 2009 - 2011 Cycle

Lindsay graduated from the Albany College of Pharmacy and Health Sciences in 2009 and went on to complete the Regulatory Pharmaceutical Fellowship specializing in drug information at Purdue University, Janssen Pharmaceuticals, and the FDA.

Upon completion of the fellowship in 2011, Lindsay joined DDI as a civilian Consumer Safety Officer (CSO). Since joining DDI Lindsay has served as a preceptor in the fellowship program and started a number of initiatives including the Global Alliance of Drug Information Specialists (GADIS).

During the fellowship Lindsay published book chapters, conducted research on biostatistical and literature evaluation knowledge and peer assessment, and provided presentations at many pharmacy conferences.

Today, Lindsay is a Team Leader and serves in the U.S. Public Health Service. In her role she oversees a variety of programs including FDA's Drug Info Rounds videos, GADIS, and the President's Emergency Plan for AIDS Relief (PEPFAR) labeling initiative. Lindsay trains CSO's to respond to questions, edits and reviews written communications for traditional and social media platforms, and serves as a supervisory resource for the Division of Drug Information team.

FELLOWSHIP TIMELINE

DRUG INFORMATION

July 2016

01

Indianapolis, IN
6 Months

PURDUE
UNIVERSITY

College of
Pharmacy

July 2016 – December 2016

02

Raritan, NJ
12 Months

janssen
PHARMACEUTICAL COMPANIES
OF JANSSEN-ILUMIN

Medical
Information

January 2017 – December 2017

03

Silver Spring, MD
6 Months

FDA

Division
of Drug
Information

January 2018 – June 2018

June 2018

DRUG INFORMATION TRACK

Purdue

The 6-month portion will expose the fellow to academia and the responsibilities of institutional-based drug information centers. The program offers experience with the provision of drug information including formulary management and drug-use policy in conjunction with IU Health and Eskenazi Health. Fellows will conduct a research project suitable for presentation at a national meeting and publication in a peer-reviewed pharmacy journal and participate in the Indiana Pharmacy Teaching Certificate Program. The fellow gains significant experience in academia, providing didactic and experiential training to student pharmacists.

Janssen

The 12-month rotation provides the opportunity for the fellow to gain experience as a member of a medical information team in a pharmaceutical industry setting. The program allows the fellow to develop skills related to development and delivery of drug information to healthcare professionals, payors, consumers, and business partners through a variety of methods. The fellow will have the option to participate in collaborative inter- and intra-departmental projects, mentor pharmacy students, and network with other pharmacists within the organization and through a pharmacist-focused resource group.

FDA

The 6-month FDA rotation will provide an opportunity for the fellow to respond to drug information requests and provide support for various FDA initiatives. The fellow will draft a Drug Safety Communication and improve the risk assessment process through increasing voluntary reporting of serious spontaneous adverse events. The fellow will be a member of the Division's Social Media team, which utilizes Twitter, Facebook, listservs, and podcasts to disseminate the latest drug information. The fellow will also lead the PEPFAR labeling initiative during their time at FDA. The fellow will also be a member of GADIS, promoting partnerships among pharmacists for the advancement of public health.

DRUG INFO PRECEPTORS

Amy H. Sheehan, PharmD

Associate Professor, Pharmacy Practice

Purdue University
College of Pharmacy



Amy graduated from the University of Cincinnati where she received her BS and PharmD degrees. After graduation, she pursued post-doctoral training through a Drug Information Practice and Pharmacotherapy Residency with the National Institutes of Health. For the past seventeen years, Amy has been working with Purdue University College of Pharmacy Department of Pharmacy Practice and the Indiana University (IU) Health Center for Medication Management. She has published over 25 peer-reviewed articles in the pharmacy literature and authored book chapters for therapeutics and drug information textbooks. Amy serves on the Indiana Pharmacy Teaching Certificate (IPTeC) Program Executive Committee and is currently a member of the Editorial Board for the *Annals of Pharmacotherapy*.

Amy is responsible for didactic instruction of the principles of drug information, including literature evaluation and interpretation of biomedical statistics, within the professional degree program at Purdue University. She serves as course coordinator for PHRM 848, "Principles of Drug Information and Literature Evaluation" and CLPH 45300, "Advanced Literature Evaluation". Amy's practice site is the IU Health Center for Medication Management located at Methodist Hospital in Indianapolis, where she contributes to the provision of comprehensive drug information services for all IU Health-affiliated hospitals throughout the state of Indiana. Amy serves as a preceptor for experiential rotations for student pharmacists, pharmacy residents, and pharmacy fellows.



DRUG INFO PRECEPTORS



Samina Ali, PharmD

**Associate Director,
Medical Information**

Janssen Scientific Affairs, LLC

Samina earned her BS and PharmD degrees from Rutgers University College of Pharmacy. Prior to joining Janssen Scientific Affairs, she completed an ASHP-accredited Hospital Pharmacy Practice Residency at the Mount Sinai Medical Center in New York City and practiced in the retail pharmacy setting with Pathmark Stores in New Jersey. While at Janssen, she continued to provide part-time support for Pathmark for almost 8 years.

Throughout her 15 plus-year career at Janssen, Samina has led and supported Medical Information activities for multiple Janssen products in oncology, virology, GI, women's health and urology, and contributed to a variety of intradepartmental projects focusing on safety, technology and professional development. Samina supported the launch of Janssen's first oral diabetes products and is currently responsible for the strategy and review of scientific responses, development of Academy of Managed Care Pharmacy (AMCP)-formatted formulary dossiers and review of promotional and sales training materials for these products. In addition, Samina participated in a one-year rotational leadership program within the Medical Information Leadership Team. She also coaches her team members on key Medical Information-related activities and mentors pharmacy students and fellows affiliated with Rutgers University and the Philadelphia College of Pharmacy. Samina is a member of the American Diabetes Association and ASHP.

CURRENT DRUG INFO FELLOWS

Megan N. Brown, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2015 – 2017 Cycle



Megan is a 2015 graduate of Mercer University College of Pharmacy in Atlanta, Georgia. Megan is currently completing the academic portion of the fellowship. In this role, she is serving as a Drug Information Specialist in the IU Health Drug Information Center where she assists with formulary and drug information requests, in addition to precepting students. Megan also assists with the "Principles of Drug Information and Literature Evaluation" course at Purdue University College of Pharmacy. In January 2016, she will begin her rotation at Janssen Scientific Affairs, LLC.

Jay R. Fajiculay, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY2
Current Fellow: 2014 – 2016 Cycle



Jay graduated from the Chicago College of Pharmacy at Midwestern University where he received his PharmD degree in May 2014. During the first six months of the fellowship, Jay served as a drug information specialist for two institutional-based drug information centers and assisted with the "Principles of Drug Information and Literature Evaluation" course at Purdue University. In January 2015, Jay began his rotation at Eli Lilly and Company, working dual-functionally in the Global Medical Information and the Global Medical Channels and eCapabilities teams. During his time at Lilly, Jay has taken the lead on multiple inter-functional global projects across Lilly business units, organized and lead monthly global team meetings, created global medical information documents, aided in strategies regarding the content and digital format of medical information disclosures and precepted pharmacy students. Throughout 2015, he returned to Purdue University to co-instruct the core drug information course and has guest lectured for various courses and professional student organizations among numerous schools of pharmacy in the Midwest and East Coast regions. Jay will begin his rotation at the FDA's Division of Drug Information in January 2016.



PAST DRUG INFO FELLOWS



Bhavini T. Parikh, PharmD

Senior Manager, Medical Information
AstraZeneca
Past Fellow: 2013 – 2015 Cycle

"Completing this fellowship was one of the best decisions I have ever made for my career. The unique program allowed me to step outside of my comfort zone, which in turn led to a great deal of professional development. I made lifelong friends and mentors along the way, and was able to explore various career fields. Upon graduating from the program, these experiences allowed me to feel prepared to start my career in any field of my choice."



Andrea M. TenBarge, PharmD

Associate Consultant, Medical Channels & Visual Media
Eli Lilly and Company
Past Fellow: 2012 – 2014 Cycle

"Choosing to complete the Regulatory Pharmaceutical Fellowship program has been one of the best decisions I have made in my career. Through my fellowship experiences, I discovered my love for innovative digital strategy and was able to land a very unique position which combined my love for medicine with my love for digital and visual media while still being able to continue my love of teaching by precepting fourth year pharmacy students. It was through my experiences with the fellowship program that led me to where I am today!"



Genevieve L. Ness, PharmD

Director, Christy Houston Foundation Drug Information Center
Assistant Professor, Pharmaceutical, Social and Administrative Sciences
Belmont University College of Pharmacy
Past Fellow: 2011 – 2013 Cycle

"The skills I obtained during the fellowship serve as the foundation of my career as a faculty member and a director of a drug information center. Bringing the three diverse perspectives to the classroom illustrates to my students the versatility of drug information skills and provides them with insight into diverse career paths. As a drug information center director, I use these skills to seek partnerships with other universities and pharmaceutical companies in addition to managing the output of drug information question responses."

PAST DRUG INFO FELLOWS

Kimberly W. Chiu, PharmD

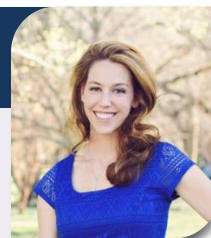
Consumer Safety Officer, Division of Drug Information
Food and Drug Administration
Past Fellow: 2010 - 2012



“The Regulatory Pharmaceutical Fellowship's unique format is a great opportunity for professional and personal growth. Professionally I developed a unique skill set which prepared me for challenging positions in a variety of settings. Personally I grew under the strong mentorship of the program's preceptors.”

Jean E. Cunningham, PharmD, BCPS

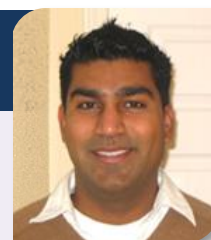
Senior Clinical Content Specialist
Truven Health Analytics
Past Fellow: 2007 - 2009



“The fellowship offered me the opportunity to build and refine my literature evaluation, drug information, and professional presentation skills (to name just a few). I was able to experience or contribute to hospital formulary management, advisory committee meetings, and promotional drug advertising standards. After completing the fellowship, I was able to secure a faculty position in drug information and continued some of the research and publication efforts I started during the fellowship. When I decided I wanted to find a position beyond academia, the fellowship experiences definitely helped me move into the drug information publishing industry. Hands down, this is one of the best investments I have made in my career.”

Sanjeev K. Bhanot, PharmD

Director, Medical Affairs
Merz Pharma Canada Ltd.
Past Fellow: 2005 - 2007



“The Regulatory Pharmaceutical Fellowship offered an opportunity for exposure to a variety of careers in pharmacy. The experiences working with government agencies, institutional practice, academia, and regulated industry provided the foundation for my career. The program was structured to provide practical knowledge and skills transferrable to many different careers within pharmacy. Seven years out of the fellowship, I still draw upon the teachings, practical knowledge from my mentors and preceptors.”



FELLOWSHIP TIMELINE

MEDICATION SAFETY

July 2016

01

Indianapolis, IN
8 Months

PURDUE
UNIVERSITY

Center for
Medication Safety
Advancement

July 2016 – February 2017

02

Indianapolis, IN
8 Months

Lilly

Surveillance and
Global Patient Safety

March 2017 – October 2017

03

Silver Spring, MD
8 Months

FDA

Office of Surveillance
and Epidemiology (OSE)

November 2017 – June 2018

June 2018

MEDICATION SAFETY TRACK

Purdue

The 8-month rotation at Purdue University College of Pharmacy's Center for Medication Safety Advancement (CMSA) will provide the fellow with exposure to academia and the various medication safety initiatives undertaken by CMSA. The fellow will actively participate in practice-based research to foster the discovery and delivery of information and practices to enhance medication safety. There will be numerous opportunities to publish original research and deliver presentations. Additionally, the fellow will have the opportunity to educate students, both didactically and through preceptorship.

Lilly

The fellow will spend an 8-month rotation at Eli Lilly and Company working on the Surveillance team within Global Patient Safety. During this time, the fellow will have opportunities to work cross-functionally between pre- and post-marketed compounds to detect and evaluate adverse effects and other problems to determine if they are drug-related. The fellow will be involved in routine surveillance work as well as participating in the development of regulatory documents to gain a foundational understanding of pharmacovigilance responsibilities within industry.

FDA

The fellow will spend the last 8 months of their tenure working in the Office of Surveillance and Epidemiology (OSE) at the FDA. During this time, the fellow will have the opportunity to participate in intra- and inter-center projects in both the pre- and post-market arenas. Additionally, the fellow will utilize adverse drug event reporting data, medical literature, and established knowledge of marketed drug products to assess postmarket safety-related issues and conduct active surveillance work.

MEDICATION SAFETY PRECEPTORS



John Hertig, PharmD, MS

**Associate Director, CMSA
Courtesy Clinical Assistant Professor of
Pharmacy Practice**

Purdue University

Dr. Hertig received his Bachelors of Science in Pharmaceutical Sciences and Doctor of Pharmacy Degree from Purdue University. Following graduation he completed a combined PGY1/PGY2 Masters in Health-System Pharmacy Administration residency at The Ohio State University Medical Center in Columbus, OH. As part of this program, he received a Masters degree in Health-System Pharmacy Administration from the Ohio State University. In his current role he assists in setting and managing the mission and vision of the organization, leads strategic initiatives, forms partnerships, educates, and acts as a catalyst to help improve the lives of patients.



Kyle Hultgren, PharmD

**Director, CMSA
Courtesy Clinical Assistant Professor of
Pharmacy Practice**

Purdue University

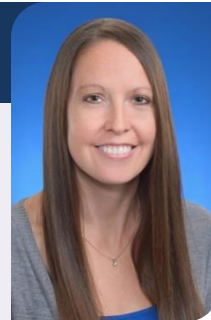
Dr. Hultgren is Managing Director of CMSA where he pursues the development of innovative safe medication use practices as well as engaging methods to educate healthcare practitioners and student pharmacists. Dr. Hultgren is a co-author of a certification program in partnership with Purdue University and the Veterans Health Administration on Lean Healthcare and Systems Redesign that has been provided to over 8,000 professionals in health systems nationwide. His current work includes predictive analytics for adverse drug events and utilizing simulation methodologies for training medical professionals on safe medication use practices. He also serves as Chairman of the Rx-SafeNet Practice Based Research Network Advisory Board for community pharmacy based medication safety research in Indiana.

MEDICATION SAFETY PRECEPTORS

Jennifer B. Mouser, PharmD

**Manager, Safety Surveillance
Global Patient Safety**

Eli Lilly and Company



Jennifer received her PharmD from Butler University. Following graduation, she worked as a retail pharmacist before accepting a safety surveillance position at Eli Lilly in Global Patient Safety. Jennifer served for several years as a safety surveillance scientist identifying and evaluating safety trends and potential safety risks for investigational and approved medications while also continuing to contribute to pharmacy practice as a part-time retail pharmacist. She now serves as the manager of the safety surveillance team comprised of scientists who are responsible for investigational and approved medications in a variety of therapeutic areas, including diabetes, cardiovascular, men's health, osteoporosis, and autoimmune disorders.

William P. Brookfield, MS

**Consultant, Safety Surveillance
Global Patient Safety**

Eli Lilly and Company



Bill obtained his pharmacy and pharmacology degrees from Butler University. Following graduation, he began his career in hospital pharmacy and served as a clinical pharmacist, an assistant director of pharmacy and a director of pharmacy over the span of 20 years. In hospital pharmacy, Bill spent time working with two outpatient clinics in diabetes and pulmonology and served as a clinical pharmacist for a family practice residency program. He precepted numerous pharmacy students in administrative and clinical hospital rotations. Bill remains actively involved in student and resident programs at Lilly. He precepts 16 to 18 PharmD students annually at Lilly. He also serves as a pharmacology professor at the University of Indianapolis in their physical therapy program and lectures in continuing education seminars for practicing physical therapists.



MEDICATION SAFETY PRECEPTORS



Irene Z. Chan, PharmD, BCPS

Commander, U.S. Public Health Service

**Deputy Director, Division of Medication
Error Prevention and Analysis (DMEPA)
Office of Surveillance and Epidemiology**

Food and Drug Administration

CDR Chan received her B.S. and Doctorate degrees in Pharmacy from Rutgers University Ernest Mario School of Pharmacy. Upon graduation, she was called to active duty and assigned to Gallup Indian Medical Center where she completed a PGY1 Pharmacy Practice Residency. She continued with the Indian Health Service for over five years in both inpatient and outpatient pharmacy settings. In 2009, she transferred to FDA. In her current role she leverages her knowledge of regulatory science, human factors, and risk management to provide oversight of safety recommendations regarding drug nomenclature, labels, labeling, packaging, and product design.



S. Christopher Jones, PharmD, MPH

Commander, U.S. Public Health Service

**Deputy Director, Division of
Pharmacovigilance II (DPV)
Office of Surveillance and Epidemiology**

Food and Drug Administration

CDR Jones earned his PharmD in 2001 from Virginia Commonwealth University (VCU). He also holds an undergraduate degree in chemistry from VCU and a Master of Public Health degree from Johns Hopkins. During pharmacy school, he joined the US Navy under a scholarship program. After graduation he was commissioned and stationed at Naval Medical Center Portsmouth. He practiced in outpatient, inpatient, and clinic settings. Following his military service, he transitioned to the U.S. Public Health Service at FDA in Silver Spring MD. Today, he is responsible for the post-marketing surveillance of adverse drug events in the Division of Pharmacovigilance II. He is involved in a variety of pharmacovigilance projects and has interests in drug safety and epidemiology.

PAST MEDICATION SAFETY FELLOWS

Katelyn Brown, PharmD

Consultant, Diabetes Real World Outcomes

Eli Lilly and Company

Past Fellow: 2013 – 2015 Cycle



Katelyn Brown graduated with her PharmD from Purdue University College of Pharmacy in 2013. Upon graduation, Dr. Brown completed the two-year post-doctoral Regulatory Pharmaceutical Fellowship in Medication Safety with Purdue University, Eli Lilly and Company, and the Food and Drug Administration.

For the first six months of her fellowship, Dr. Brown conducted research and lead state initiatives on improving medication safety through the Center for Medication Safety Advancement (CMSA) at Purdue University College of Pharmacy. She also developed and served as course coordinator for a Pharmaceutical Industry elective at Purdue University College of Pharmacy. Once at Eli Lilly and Company, Dr. Brown served as a surveillance scientist in Global Patient Safety where she completed pharmacovigilance activities for several compounds and was responsible for authoring regulatory requirements to the FDA and EMA. In her final nine months, Dr. Brown was at the FDA in the Office of Surveillance and Epidemiology where she split her time between the Division of Pharmacovigilance (DVP) and the Division of Medication Error and Prevention Analysis (DMEPA). While in DPV, Dr. Brown was responsible for pharmacovigilance activities including evaluating safety signals and identifying appropriate risk mitigation plans. She was also involved with the Mini-sentinel project. While in DMEPA, Dr. Brown participated in human factor reviews and name safety analyses.

Following her completion of the fellowship, Dr. Brown accepted a full-time position at Eli Lilly and Company as a Therapeutic Consultant for Diabetes in US Health Outcomes.



ADVERTISING & PROMOTION TRACK

Track Overview

The two-year, Advertising & Promotion track, prepares the fellow with an opportunity to develop an understanding of the FDA regulations, industry codes, policies, and Federal and State laws as it relates to prescription drugs and biologics advertising and promotion activities. The fellow will also have an opportunity to gain experience in the government promotional review process and become familiar with sections of the Federal Food, Drug, and Cosmetic Act and relevant FDA Guidance documents. Finally, the fellow will gain significant experience in academia providing didactic and experiential training of students.

The Advertising & Promotion track plans to recruit a 2017 - 2019 fellow

For more information, please contact:

DrugMarketingFellowship@gmail.com

FELLOWSHIP BENEFITS



Competitive stipend

Reimbursement for relocation and professional travel expenses



Enrollment in the Indiana Pharmacy Teaching Certificate Program

Purdue University benefits package (i.e. health insurance, prescription coverage, vision plan, dental)



Vacation and University holidays

1 year membership in the Regulatory Affairs Professionals Society



APPLICATION PROCESS

The fellow must be a graduate from an ACPE-accredited college of pharmacy, or otherwise eligible for licensure, prior to the start of the fellowship term.

Preliminary interviews are conducted during PPS at the American Society of Health-System Pharmacists Midyear Clinical Meeting annually. Participation in PPS is not required but is encouraged for applicants.

All interested applicants must submit the following:

1. Letter of intent for one of the two tracks
2. Contact information for three references
3. Curriculum Vitae
4. Official transcripts (electronic copies OK)

All application materials should be submitted electronically to the email contacts below no later than **11:59 pm EDT on Wednesday, December 16, 2015.**

Drug Information Track:

DrugInformationFellowship@gmail.com

Medication Safety Track:

MedicationSafetyFellowship@gmail.com

On-site interviews will take place at the FDA in Silver Spring, MD on Friday, January 8, 2016. For more information, please visit our website at:

<http://www.fda.gov/RegPharmFellowship>.

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2016 – 2018 CYCLE

